

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicants | Guy E. Home, Jr., <i>et al.</i> |
| Application No. 10/766,295 | Filing Date: January 27, 2004 |
| Title of Application: | Composite Flexible Endoscope Insertion Shaft With Tubular Substructure |
| Confirmation No. 9340 | Art Unit: 3739 |
| Examiner: | Matthew John Kasztejna |

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Appeal Brief Under 37 CFR §41.37

Dear Sir:

A Notice of Appeal from the final rejection of Claims 1-7 and 10-13, all pending claims of U.S. Patent Application No. 10/766,295, being filed on May 28, 2008, Appellant accordingly files its Appeal Brief in connection with the appeal. A Claims Appendix is submitted herewith, as are Appendices related to evidence previously submitted and decisions related to the case.

(i) Real Party In Interest

The real party in interest is Karl Storz Endovision, Inc., 91 Carpenter Hill Road, Charlton, MA, 01507.

(ii) Related Appeals and Interferences

Appellant knows of no other prior or pending appeals, interferences, or judicial proceedings related to the instant Appeal.

(iii) Status Of Claims

Claims 8-9 and 14-15 have been cancelled. Claims 1-7 and 10-13 stand rejected and are the subject of the instant Appeal. A copy of each of these claims is attached hereto in the Claims Appendix.

(iv) Status Of Amendments

No Amendments have been filed since the outstanding Final Office Action was mailed on February 28, 2008.

(v) Summary Of Claimed Subject Matter

Claims 1 and 13 are the rejected independent claims and are discussed below.

Independent Claim 1

Claim 1 is directed to an endoscope insertion shaft, which includes a tubular member (102), a sheath (128), and a barrier layer (104). The tubular member (102) has an axis (120) and includes a continuous wall to form a closed interior (see Fig. 4) and the continuous wall includes at least one aperture (118) for increasing the flexibility of the tubular member (102). (Page 4 line 14 – page 5 line 8; Fig. 3). The sheath (128) includes the following layers: a braided layer (106), a laminating layer (108), and a wear layer (110). (Page 6 lines 6-20; Fig. 1). The braided layer (106) jackets the continuous wall of the tubular member (102). (Page 6 lines 6-20).

The barrier layer (104) comprises a polyester wrap and is disposed between the continuous wall of the tubular member (102) and the braided layer (106) of the sheath (128). (Page 6 lines 6-20, Fig. 1). The barrier layer (104) jackets the tubular member (102) to form a seal along the length of the tubular member (102). (Page 6 lines 6-20; Fig. 1).

Thus, the endoscope insertion shaft of claim 1 includes four layers over the tubular member (102), which are disposed in a particular order: the barrier layer (104), the braided layer (106), the laminating layer (108), and the wear layer (110)

Independent Claim 13

Claim 13 is also directed to an endoscope insertion shaft that includes a tubular member having an axis (120) and including a continuous wall to form a closed interior

(see Fig. 4). The continuous wall includes at least one aperture (118) for increasing the flexibility of the tubular member (102). (Page 4 line 14 – page 5 line 8; Fig. 3).

A barrier layer (104) jackets the tubular member (102) to form a seal extending along the length of the tubular member (102) around the continuous wall. (Page 6 lines 6-20; Fig. 1). The barrier layer (102) is jacketed by a braided layer (106). (Page 6 lines 6-20; Fig. 1).

The endoscope insertion shaft also includes a laminating layer (108) and a wear layer (110). (Page 6 lines 6-20; Fig. 1). At least the barrier layer (102), the braided layer (106), and the laminating layer (108) are formed as a single composite structure.

The endoscope insertion shaft of claim 13 includes four layers over the tubular member (102), disposed in a particular order: the barrier layer (104), the braided layer (106), the laminating layer (108), and the wear layer (110).

(vi) Grounds Of Rejection To Be Reviewed On Appeal

Claims 1-7 and 10-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,275,152 to Krauter et al. ("Krauter") in view of U.S. Patent No. 6,749,560 to Konstorum et al. ("Konstorum") and further in view of U.S. Patent No. 6,540,669 to Abe et al. ("Abe").

(vii) Argument

Rejection of Claims 1-7 and 10-13 under 35 U.S.C. 103(a)

Appellant respectfully submits that the invention of claims 1-7 and 10-13 would not have been obvious to a person of ordinary skill in the art at the time the invention was made. The Examiner has rejected claims 1-7 and 10-13 under 35 U.S.C. § 103(a) over Krauter in view of Konstorum and Abe. The invention of claims 1-7 and 10-13 is neither anticipated nor obvious over the cited references.

First, all claims recite an endoscope insertion shaft that comprises a tubular member including a continuous wall. All claims also recite that the tubular member is sheathed or jacketed by four distinct layers in a particular order: a barrier layer jacketing the tubular member, a braided layer jacketing the barrier layer, a laminating layer, and a wear layer.

Krauter discloses an insertion tube body for an endoscope. The tube body 15 has a helical monocoil 21 extending along its length. (Krauter, col. 3 lines 40-41). A tubular sleeve or jacket 22 of urethane is disposed over the monocoil 21 and a tubular braid layer 23 is disposed over the jacket 22. (Krauter, col. 3 lines 43-45). A coating 24 of polyurethane impregnates and adheres to the braid 23 and to the jacket 22 and forms an outer skin for the insertion tube body 15. (Krauter, col. 3 lines 46-49). This arrangement is clearly shown in FIG. 2 of Krauter. Thus, Krauter discloses an endoscope insertion shaft having only three layers jacketing a tubular member (the

monocoil 21), as the Examiner acknowledges on page 3 of the Office Action of February 28, 2008.

Abe discloses a flexible tube for an endoscope having a core body 2 and an outer cover 3. (Abe, col. 4, lines 52-54). The core body 2 includes a helical coil 21 formed from a flat metal band and a reticular tube 22 formed of braided metal or nonmetal fine wires. (Abe, col. 4 line 58 – col. 5 line 14). The outer cover 3 covers the outer periphery of the core body 2. (Abe, col. 4 lines 52-54). In one embodiment, the outer cover 3 is a laminated structure that includes an inner layer 32, an intermediate layer 33, and an outer layer 34. (Abe, col. 10 lines 39-42). Thus, Abe discloses an outer cover having three layers that jackets a braided layer (reticular tube 22). While Abe discloses four layers jacketing the helical coil 21, Abe teaches that these layers are disposed in a particular order that differs significantly from the order of the layers in claims 1 and 13. Abe specifically teaches that all of the layers of the outer cover 3 jacket the braided reticular tube 22. That is, Abe does not disclose any barrier layer between the braided layer and the helical coil 21.

Abe also contains specific teachings relating to the functions of the outer layer and its constituent parts. Abe teaches that the inner layer 32 is formed of a material that adheres well with a coating 231 that is deposited on parts of the reticular tube 22. (Abe, col. 11, lines 1-4). Coating 231 is deposited over at least one of the fine wires 23 for the purpose of forming a strong bond between the reticular tube 22 and the outer

cover 3. (Abe, col. 5, lines 21-35). The material of the inner layer 32 is also selected to be suitable for forming protruding portions 31, which serve to anchor the outer cover 3 to the core body 2. The protruding portions 31 protrude from the outer cover 3 and engage with (fill in) the holes and concave portions of the outer periphery of the core body 2. (Abe, col. 7, lines 25-44). FIG. 5 provides a helpful view of this aspect of the device of Abe.

Konstorum discloses an endoscope shaft that includes a slotted tube. The slotted tube is made of a superelastic alloy and has slots formed along one or more sections of the tube's length. (Konstorum, col. 1, lines 19-34). The slots in the tube are arranged to increase the flexibility of the tube. (Konstorum, col. 1, lines 47-48). The endoscope shaft also includes a cover 32 comprised of a resilient plastic or polymer material. (Konstorum, col. 5, lines 7-8). The cover 32 is directly attached to the tube 40. (Konstorum, col. 5, lines 14-15). Konstorum, thus, only discloses use of only one layer over the tubular member (tube 40).

Thus, none of the cited references disclose an endoscope insertion shaft that includes four layers over a tubular member, disposed in the particular order recited by the claims.

The Examiner, however, has argued that it would have been obvious for one of ordinary skill in the art to include an additional, outer "wear layer " in the sheath of Krauter to provide a cover that will suffer very little degradation even over repeated

cleaning and sterilization as taught by Abe. (Office Action of Feb. 28, 2008, page 3).

The Examiner provided additional insight into his argument in the Advisory Action mailed on May 1, 2008. The Examiner stated therein that it would have been obvious to include the outer layer of Abe in the apparatus of Krauter to provide an outer layer whose physical properties can be readily controlled to desired specifications. (Advisory Action of May 1, 2008, Continuation Sheet).

It is the Examiner's burden to establish *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). Obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). In the present case, the Examiner's reasoning concerning what would have prompted the skilled worker to have arranged the elements taught in the prior art in the manner necessary to reach the claimed invention is critically flawed. As such, Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness.

Appellant respectfully submits that one of ordinary skill in the art would never have been motivated to include the outer layer of Abe on the device of Krauter. Krauter explicitly teaches that the polyurethane coating 24 is an "outer skin" for the insertion tube body 15. (Krauter, col. 3 lines 46-49). The coating 24 disclosed by Krauter is

intended to be a cover to provide protection to the insertion tube body. Krauter discloses that "the polyurethane or similar material" coats the braided layer and provides a "smooth, tough outer skin." (Krauter, col. 2 lines 32-36). Clearly, Krauter teaches that the polyurethane coating 24 is an outer cover intended to protect the insertion tube. Abe teaches that the outer cover 3, particularly the outer layer 34, serves the same purpose. Abe discloses: "The outer layer 34 is preferably formed of a material having chemical resistance...[and] will suffer very little degradation even over repeated cleaning and sterilization." (Abe, col. 11 lines 58-61). In fact, there is no appreciable difference between the "outer skin" coating 24 of Krauter and the outer layer disclosed in Abe. Abe teaches an outer layer 34 and teaches that this layer is preferably formed of a material having chemical resistance and that will suffer very little degradation over repeated cleaning and sterilization. (Abe, Col. 11, lines 58-61). Further, Abe explicitly teaches that the outer layer 34 could be made out of polyurethane (Abe, Col. 11 line 66 – Col. 12 line 5), which is precisely the material that Krauter teaches to use for its "outer skin" coating 24. The outer cover of Abe is what the Examiner submits that one of skill in the art would have wanted to include on the device of Krauter. However, since Krauter already includes an outer "wear layer," which serves the same purpose as the outer layer of Abe and is made of the same material, one of ordinary skill in the art would not have been motivated to include the outer layer of Abe in Krauter, as this would have been superfluous.

Additionally, if Abe would have provided any motivation at all to one of ordinary skill in the art, the motivation would have been to change the material of the outer coating 24 of Krauter. Abe provides, at Column 12, lines 1 – 14, a lengthy list of material disclosed to be suitable for use as the outer layer 34. One of ordinary skill in the art reading the disclosure of Abe may have been motivated to select an alternative material for use as the outer skin coating 24 of Krauter, but Abe contains nothing that would motivate that person to add a layer to the device of Krauter.

Appellant further submits that the teaching of Abe would have led one of ordinary skill in the art away from including the outer layer disclosed therein on the device of Krauter. The outer layer of Abe would not work with the layer arrangement taught by Krauter in the way intended by the express teaching of Abe. Abe discloses that:

[t]he tips of the protruding portions 31 [which are part of the outer cover 3] that protrude into the concave portions are formed so as to reach the outer periphery of the coil 21. The protruding portions 31 that protrude into the holes are formed to be even longer in order for the tips thereof to extend into the gaps 25 of the coil 21.

(Abe, col. 7 lines 32-37). However, the endoscope of Krauter includes a jacket 22 between the monocoil 21 and the braid layer 23. (Krauter, col. 3 lines 43-46). This jacket 22 would prevent any protrusions formed by an outer layer from reaching through the braid layer and into the gaps in the monocoil, which goes against the express teaching of Abe. One of ordinary skill in the art would have recognized that the outer

layer of Abe would not have worked with the later arrangement of Krauter, and would not have been motivated to include such an outer layer on that basis.

For at least the foregoing reasons, Appellant respectfully submits that the claimed endoscope insertion shaft is not obvious in light of the cited references and is patentable. One of ordinary skill in the art would never have been motivated to make the combination submitted by the Examiner.

Conclusion

As Appellant has made a significant advance over the prior art, reconsideration and allowance of all pending claims is believed in order, and such action is earnestly solicited.

Respectfully submitted,

/Wesley W. Whitmyer, Jr./

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Wesley W. Whitmyer, Jr., Registration No. 33,558
Todd M. Oberdick, Registration No. 44,268
Attorneys for Appellant
ST.ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, CT 06905-5619
203 324-6155
Attorneys for Appellant

**Claims Appendix
to Appeal Brief Under 37 CFR §41.37
Serial No. 10/766,295**

1. An endoscope insertion shaft comprising:
 - a tubular member including a continuous wall to form a closed interior, said tubular member having an axis and said continuous wall including at least one aperture for increasing the flexibility thereof; and
 - a sheath comprising at least the following layers:
 - a braided layer;
 - a laminating layer;
 - a wear layer;wherein the braided layer jackets the continuous wall of said tubular member; and
 - a barrier layer comprising a polyester wrap is disposed between the continuous wall of said tubular member and the braided layer and jackets the tubular member to form a seal therebetween along the length of the tubular member.
2. The endoscope insertion shaft as set forth in Claim 1 wherein the at least one aperture comprises a pattern of apertures.
3. The endoscope insertion shaft as set forth in Claim 2 wherein the pattern of apertures comprises a first set of apertures positioned along a line parallel to the axis of the tubular member.
4. The endoscope insertion shaft as set forth in Claim 3 wherein the first set of apertures comprises at least one elongated aperture having an axis oriented at an angle to the axis of the tubular member.

5. The endoscope insertion shaft as set forth in Claim 4 wherein the angle is in the range from zero to ninety degrees.
6. The endoscope insertion shaft as set forth in Claim 2 wherein the pattern of apertures comprises a pair of apertures.
7. The endoscope insertion shaft as set forth in Claim 2 wherein the apertures are circumferentially positioned on the tubular member.
10. The endoscope as set forth in Claim 1 wherein the laminating layer jackets the braided layer.
11. The endoscope as set forth in Claim 10 wherein the wear layer jackets the laminating layer.
12. The endoscope as set forth in Claim 1 wherein the sheath comprises a composite material.
13. An endoscope insertion shaft comprising:
 - a tubular member including a continuous wall to form a closed interior, said tubular member having an axis and including at least one aperture for increasing the flexibility thereof;
 - a barrier layer jacketing the tubular member to form a seal extending along the length of said tubular member around said continuous wall of said tubular member;
 - a braided layer jacketing the barrier layer;
 - a laminating layer;
 - a wear layer;

wherein at least said barrier layer, said braided layer and said laminating layer are formed as a single composite structure.

**Evidence Appendix
to Appeal Brief Under 37 CFR §41.37
Serial No. 10/766,295**

None.

**Related Proceedings Appendix
to Appeal Brief Under 37 CFR §41.37
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None.